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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,655	01/16/2002	Damian J. Gallina	01-496-A	7537
20306	7590	10/03/2003	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 CHICAGO, IL 60606			WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/050,655	GALLINA, DAMIAN J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RANDALL WINSTON	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to pharmaceutical composition for preventing or treating an HIV infection comprising hyaluronidase enzyme, classified in class 424, subclass 96.62, for example.
  - II. Claim 2, drawn to a method for preventing or treating an HIV infection in a patient comprising administering to a patient in need of HIV prevention or treatment the pharmaceutical composition of claim 1, classified in class 424, subclass 208, for example.
  - III. Claims 3-5, drawn to a pharmaceutical composition comprising a hyaluronidase treated HIV virus, classified in class 424, subclass 96.62, for example.
  - IV. Claims 6-8, drawn to a method for preventing or treating an HIV infection in a patient comprising administering to a patient in need of HIV prevention or treatment the pharmaceutical composition of claim 3, classified in class 424, subclass 94.1, for example.
  - V. Claims 9-10, drawn to a pharmaceutical composition comprising an anti-HIV infection amount of antigen presenting cells that have been sensitized

with hyaluronidase treated HIV infected cells, classified in class 424, subclass 96.62, for example.

- VI. Claims 11-12, drawn to a pharmaceutical composition comprising an anti-HIV infection amount of antigen presenting cells that have been sensitized with hyaluronidase treated HIV virus, classified in class 424, subclass 94.1, for example.
- VII. Claims 13-14, drawn to a method of preventing or treating HIV infection in a patient comprising administering to a patient in need of HIV prevention or treatment the pharmaceutical composition of claim 9, classified in class 424, subclass 208.1, for example.
- VIII. Claims 15-16, drawn to a method of preventing or treating HIV infection in a patient comprising administering to a patient in need of HIV prevention or treatment the pharmaceutical composition of claim 11, classified in class 424, subclass 208.1, for example.
- IX. Claims 17-19, drawn to an anti-HIV vaccine comprising a hyaluronidase treated HIV virus, classified in class 424, subclass 184.1, for example.

- X. Claims 20-22, drawn to a method of inducing or enhancing an immune response in a patient, the method comprising administering to the patient the anti-HIV vaccine of claim 17, classified in class 424, subclass 184.1, for example.
  - XI. Claim 23, drawn to a method of inducing or enhancing immunity in a patient in need of such treatment in order to initiate responses comprising administering to said patient a hyaluronidase enzyme, classified in class 424, subclass 208.1, for example.
  - XII. Claim 24, drawn to a pharmaceutical composition used to initiate immune responses to pathogens or pathogen infected cells in a patient comprising hyaluronidase enzyme, classified in class 424, subclass 96.62, for example.
2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These claimed methods such as Inventions II, IV, VII, VIII, X, XI, methods are distinguishable, each from the other, because they are six unrelated methods. The six method's preamble and/or objectives are either a method for preventing or treating an HIV infection in a patient utilizing different compositions as demonstrated by (Invention II, e.g. claim 1 composition—Invention IV, e.g.

claim 3 composition—Invention VII, e.g. claim 9 composition—Invention VIII, e.g. claim 11 composition) or a method of inducing or enhancing an immune response in a patient utilizing different compositions as demonstrated by (Invention X, e.g. claim 17 composition—Invention XI, e.g. hyaluronidase enzyme product). Therefore, these six unrelated methods utilize different compositions to achieve its preamble objective.

Moreover, the claimed compositions such as Inventions I, III, V, VI, IX, XII are distinguishable, each from the other, because they are six unrelated compositions. The six unrelated compositions are either a pharmaceutical composition for preventing or treating an HIV infection composition *hyaluronidase enzyme* or pharmaceutical composition comprising an anti-HIV infection amount of antigen presenting cells that have been sensitized with *hyaluronidase treated HIV infected cells* or a pharmaceutical composition comprising an anti-HIV infection amount of antigen presenting cells that have been sensitized with *hyaluronidase treated HIV infected virus* or an anti-HIV vaccine comprising a *hyaluronidase treated HIV virus* or a pharmaceutical composition used to initiate immune responses comprising *hyaluronidase enzyme*. Therefore, these unrelated compositions will have to contain different amounts to obtained its objective.

Furthermore, the compositions and/or methods are not disclosed as capable of use together because they have different modes of operation,

they have different functions, and/or they have different effects. One would not have to practice the various methods and/or use the various compositions at the same time to practice just one method alone and/or one composition alone.

3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Applicant is advised that the reply to this requirement to be completed must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

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An inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**